Complete Summary

GUIDELINE TITLE

Aspects of primary care for the HIV-infected substance user.

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Aspects of primary care for the HIV-infected substance user. New York (NY): New York State Department of Health; 2004. 17 p. [36 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Human immunodeficiency virus (HIV) infection
- Substance use
- Viral hepatitis in HIV-infected substance users:
  - Hepatitis A virus infection
  - Hepatitis B virus infection
  - Hepatitis C virus infection
  - Late sequelae of viral hepatitis:
    - Cirrhosis
    - End-stage liver disease (ESLD)
    - Hepatocellular carcinoma
- Tuberculosis
- Sexually transmitted diseases in HIV-infected substance users:
  - Syphilis
  - Genital ulcers

    - Gonorrhea
    - Chlamydia
- Soft tissue disorders (abscesses) in HIV-infected substance users:
    - *Staphylococcus aureus*
    - Methicillin-resistant *Staphylococcus aureus*
    - Facultative gram-negative bacteria
    - Mixed anaerobic bacteria
    - *Clostridium tetani* (tetanus clusters)
    - *Clostridium botulinum* (wound botulism)
- Necrotizing skin and soft tissue infections
- Overdose from heroin, other opioids, or cocaine

GUIDELINE CATEGORY

Counseling
Diagnosis
Evaluation
Management
Prevention
Risk Assessment
Screening
Treatment

CLINICAL SPECIALTY

Allergy and Immunology
Family Practice
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology
Preventive Medicine
Psychiatry
Psychology

INTENDED USERS

Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Public Health Departments
Substance Use Disorders Treatment Providers

GUIDELINE OBJECTIVE(S)

To provide primary care recommendations on selected conditions which may have greater prevalence among human immunodeficiency virus (HIV)-infected substance users, or which may have particular diagnostic, preventive, or therapeutic implications in this diverse patient population

TARGET POPULATION

- Human immunodeficiency virus (HIV) infected substance users and their drug sharing, sexual, and household contacts
- Intravenous drug users

INTERVENTIONS AND PRACTICES CONSIDERED

Viral Hepatitis

1. Prevention
    - Screening for hepatitis A, B, C
    - Hepatitis A vaccine
    - Hepatitis B vaccine
    - Combined hepatitis A and B vaccine
    - Vaccination of drug-sharing, sexual, and household contacts
    - Risk reduction counseling for hepatitis A, B, and C
    - Referral to sources of sterile-injection equipment, syringe exchange programs, and pharmacy sales
2. Evaluation of chronically infected or co-infected hepatitis patients for liver disease
3. Treatment options for Hepatitis B:
    - Tenofovir*
    - Emtricitabine
    - Interferon alfa-2b
    - Lamivudine (as a component of highly active antiretroviral therapy [HAART])
    - Adefovir
4. Counseling hepatitis C patients to discontinue alcohol consumption

Tuberculosis

1. Purified protein derivative (PPD) tuberculin skin test
2. Chest radiograph
3. Expedited treatment
4. Directly observed therapy (DOT)
5. Pharmacotherapy:
    - Isoniazid
    - Pyridoxine
    - Rifampin/pyrazinamide (not recommended for latent TB)
6. Monitoring of serum liver enzymes

Sexually Transmitted Diseases (STDs)

1. Behavioral risk reduction counseling
2. Screening
    - Syphilis
    - Cervical screening for gonorrhea and chlamydia
    - Urine-based testing for gonorrhea and chlamydia
3. Diagnosis (of syphilis)
    - Non-treponemal tests
    - Treponemal tests (recommended)
    - Fluorescent treponemal antibody-absorption (FTA) tests

Soft-Tissue Disorders

1. Counseling on risk reduction for soft-tissue infections
2. Draining and packing abscesses
3. Culture and sensitivity testing when pus can safely be obtained

Overdose

1. Counseling on risk and prevention of overdose
2. Methadone maintenance
3. Training in resuscitation
4. Provision of naloxone

***Note from the National Guideline Clearinghouse™**: The U.S. Food and Drug Administration's (FDA) MedWatch Safety program distributed information from the manufacturer (Gilead Sciences, Inc) of tenofovir disoproxil fumarate (Viread®) about a high rate of early virologic failure and emergence of nucleoside reverse transcriptase inhibitor (NRTI) resistance associated mutations with the use of the drug in a once-daily triple NRTI regimen along with didanosine enteric coated beadlets (Videx EC, Bristol-Myers Squibb), and lamivudine (Epivir, GlaxoSmithKline). Based on these results, Tenofovir DF in combination with didanosine and lamivudine is not recommended when considering a new treatment regimen for therapy-naïve or experienced patients with HIV infection. Patients currently on this regimen should be considered for treatment modification. For more information, visit the FDA Web site.

MAJOR OUTCOMES CONSIDERED

- Incidence of viral hepatitis infection in HIV-infected substance users
- Incidence of viral hepatitis infection in social contacts
- Incidence of viral hepatitis community outbreaks
- Incidence and onset of late hepatic sequelae
- Hepatitis C treatment adherence
- Sustained viral response for hepatitis C treatment
- Rates of tuberculosis infection (active and latent)
- Rates of sexually transmitted diseases
- Prevalence of abscesses
- Overdose related mortality
- Efficacy of risk-reduction interventions

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Quality of Evidence

I. At least one randomized trial with clinical results
II. Clinical trials with laboratory results
III. Expert opinion

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Human Immunodeficiency Virus (HIV) Guidelines Program works directly with committees composed of HIV Specialists to develop clinical practice guidelines. These specialists represent different disciplines associated with HIV care, including infectious diseases, family medicine, obstetrics and gynecology, among others. Generally, committees meet in person three to four times per year, and otherwise conduct business through monthly conference calls.

Committees meet to determine priorities of content, review literature, and weigh evidence for a given topic. These discussions are followed by careful deliberation to craft recommendations that can guide HIV primary care practitioners in the delivery of HIV care. Decision making occurs by consensus. When sufficient evidence is unavailable to support a specific recommendation that addresses an important component of HIV care, the group relies on their collective best practice experience to develop the final statement. The text is then drafted by one member, reviewed and modified by the committee, edited by medical writers, and then submitted for peer review.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

For substance users in methadone maintenance treatment programs, on-site directly observed therapy (DOT) may be a valuable adherence-promoting strategy and can be both cost-effective and cost-saving from a societal perspective. When feasible, incentives which offer positive reinforcement to substance users, including monetary incentives, seem to be both effective at increasing rates of adherence to tuberculosis (TB) services and justifiable on a cost basis. Similarly, directly observed therapy for latent tuberculosis infection may be used to increase completion rates in congregate settings (e.g., penal institutions, residential facilities, shelters) or in ambulatory clinical settings that are attended on a frequent basis (e.g., methadone maintenance programs, dialysis units).

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The quality of evidence (I-III) is defined at the end of the "Major Recommendations" field.

Viral Hepatitis

- All human immunodeficiency virus (HIV) infected patients should be tested at baseline for evidence of hepatic injury. (II)

  Key Points:

  - Substance users are at high risk for infection with hepatitis viruses A, B, and C (HAV, HBV, and HCV).
  - Infection among substance users may initiate and amplify hepatitis outbreaks.

Hepatitis A Virus (HAV)

- Clinicians should offer HIV-infected substance users who do not have antibody evidence of previous exposure (i.e., who are susceptible to hepatitis A) the hepatitis A vaccine. (II) The full series should be given (initial dose and a second dose six to twelve months later) to ensure maximal antibody response.

- Routine post-vaccination antibody measurement is not recommended because of the generally high efficacy of the vaccine. (II)

Key Point:

- Clinicians should periodically readdress vaccination with individuals who initially decline either hepatitis A or hepatitis B vaccination.

Hepatitis B Virus (HBV)

- Clinicians should offer the hepatitis B vaccine to HIV-infected substance users who have been identified by serology to be susceptible to hepatitis B. (II)
- Clinicians should strongly encourage all HIV-infected patients who do not have serologic evidence of prior HBV infection, or who have not previously received the complete series of HBV vaccine, to receive the hepatitis B vaccination series. Serologic testing for anti-HBs one to two months after the third dose should be performed. If the patient did not respond to the vaccine series, the clinician should administer a second series when the patient's CD4 count is $\geq$200 cells/mm^3.(III)
- HIV-infected substance users who continue to inject drugs should receive counseling regarding the risk of HBV infection from non-sterile injection practices. These patients should be referred to sources of sterile injection equipment (such as syringe exchange programs and pharmacy sales). (II)
- Clinicians should evaluate HIV-infected substance users chronically infected with hepatitis B (or co-infected with hepatitis B and C) for liver disease. These patients should be evaluated and offered treatment when medically indicated according to current guidelines. (I)
- Clinicians should inform and advise HIV-infected substance users chronically infected with hepatitis B (or co-infected with hepatitis B and C) that sharing injection equipment and engaging in unprotected sex place their partners at risk for transmission of both HIV and viral hepatitis. (II)
- Clinicians should advise HIV-infected substance users chronically infected with hepatitis B that drug-sharing, sexual, and household contacts may be at risk for hepatitis B. Such contacts should be advised to undergo medical evaluations and, if susceptible, should be offered HBV vaccination. (II)
- The drug regimen of choice is currently unknown because no randomized comparative trials have been conducted in this patient population. Options include tenofovir, emtricitabine, interferon alfa-2b, lamivudine, or adefovir; there are insufficient data to recommend combinations of drugs at this time. If lamivudine is given for treatment of hepatitis B, it should never be used alone but in combination with other HIV-active antiretroviral agents as a component of highly active antiretroviral therapy (HAART).

Key Point:

- HBV vaccination is indicated for all HIV-infected substance users who are susceptible and may be particularly important for those co-infected with HCV.

Hepatitis C Virus (HCV)

- Clinicians should perform annual HCV screening to detect recent infections for HIV-infected substance users who do not have antibody evidence of previous exposure (i.e., who are found to be susceptible to HCV) and who continue to engage in risk behaviors. (III)
- HIV-infected substance users who continue to inject substances and who are found to be susceptible to hepatitis C should receive counseling regarding the risk of HCV infection from non-sterile injection practices. These patients should be referred to sources of sterile injection equipment (such as syringe exchange programs and pharmacy sales). (II)
- Clinicians should evaluate HIV-infected substance users chronically infected with hepatitis C (or co-infected with hepatitis B and C) for liver disease. These patients should be evaluated and offered treatment when medically indicated according to current guidelines. (I)
- HIV-infected substance users chronically infected with hepatitis C (or co-infected with hepatitis B and C) should be counseled to avoid sharing injection equipment or engaging in unprotected sex because their partners will then be at risk for transmission of both HIV and viral hepatitis. (II)
- Substance-sharing contacts should be advised to undergo medical evaluations. (II) As part of this medical evaluation, all contacts should be offered testing for HIV and hepatitis C.
- Clinicians should advise HIV/HCV co-infected patients and patients infected with HCV alone to discontinue consumption of alcohol.

Key Point:

- HCV seems to be more easily transmitted parenterally than HIV.

Prevention

Table: Viral Hepatitis Risk Reduction Guidance for Substance Users

- Stop using illicit drugs – substance users who wish to stop using drugs should be referred to substance abuse treatment when indicated.
- If unable to stop using illicit drugs, substance users should stop injection of illicit drugs.
- If unable to stop injection of illicit drugs, substance users should use a new, sterile needle for every injection.
- Substance users should use their own needle, syringe, filtration cotton, and cooker, without sharing with others.
- If assisting others with injections, the substance user should wash hands thoroughly between injections and use all new equipment.
- Substance users should know their own HIV, hepatitis B, and hepatitis C status, should not engage in unprotected sex, and should be advised to avoid sharing injection equipment.

Effect of Substance Use and Abuse Treatment on HCV Disease Progression and Treatment

Key Point:

- Clinicians should be guided by patients' symptoms (e.g., opioid craving or oversedation) when considering whether a change in methadone or buprenorphine dose is indicated.

Treatment and Adherence

Key Point:

- Adherence to the HCV treatment regimen is difficult for all patients, not just substance users or those with HIV.

Tuberculosis (TB)

- Clinicians should perform a purified protein derivative (PPD) tuberculin skin test at baseline for HIV-infected substance users. (II)
- Clinicians should evaluate HIV-infected substance users who have a reactive tuberculin skin test and should obtain a chest radiograph to exclude active tuberculosis. (I)
- HIV-infected substance users with active tuberculosis should receive expedited treatment (I), and strong consideration should be given to directly observed therapy (DOT). (II)
- Clinicians should evaluate HIV-infected substance users who have latent TB infection, and, in the absence of medical contraindications or previous completion of preventive therapy, these patients should be offered treatment for latent TB infection. (I)
- To identify recent infections, clinicians should obtain annual PPD tuberculin skin tests in HIV-infected substance users whose skin test results were negative for tuberculosis at baseline. (II)

Key Points:

- Rifampin may increase the catabolism of opioids and can precipitate opioid withdrawal in opioid users or those on methadone maintenance regimens unless methadone doses are increased.
- Co-locating TB services may improve adherence and rates of treatment completion

Sexually Transmitted Diseases (STDs) in HIV-Infected Substance Users

- Clinicians should reinforce behavioral risk-reduction measures for STD prevention, including consistent condom use.

Key Point:

- Primary care clinicians play an important role in reinforcing behavioral risk-reduction measures.

Screening for STDs in HIV-Infected Substance Users

- Clinicians should screen HIV-infected substance users for syphilis.

- Clinicians should screen female HIV-infected substance users annually for cervical gonorrhea and chlamydia.

Soft-Tissue Disorders

- Clinicians should counsel intravenous drug users (IDUs) on risk reduction for soft-tissue infections (see Tables 3 and 4 in the original guideline document).

Overdose

- Clinicians should counsel substance-using patients about the risk of overdose and how it may be prevented.

Heroin and Other Opioids

Key Point:

- Methadone maintenance has been demonstrated to be an effective preventative measure for overdose.

Definitions

Quality of Evidence

I. At least one randomized trial with clinical results
II. Clinical trials with laboratory results
III. Expert opinion

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

This guideline may help the clinician provide appropriate primary care management of the human immunodeficiency virus (HIV)-infected substance user.

POTENTIAL HARMS

- Persons co-infected with human immunodeficiency virus (HIV) and hepatitis B virus (HBV) and/or hepatitis C virus (HCV) who are receiving highly active antiretroviral therapy (HAART) are more likely to survive to be at risk for the late sequelae of chronic HBV and HCV infection, including cirrhosis, end-stage liver disease (ESLD), and hepatocellular carcinoma.
- If lamivudine is given for treatment of hepatitis B, it should never be used alone but in combination with other HIV-active antiretroviral agents as a component of HAART.
- Patients actively using alcohol or injecting drugs may experience increased toxicity from HCV therapies.
- Rifampin may increase the catabolism of opioids and can precipitate opioid withdrawal in opioid users or those on methadone maintenance regimens unless methadone doses are increased.
- For individuals receiving disulfiram for management of alcoholism, metronidazole may precipitate abdominal distress, nausea, vomiting, flushing, and headache. Liquid preparations of some antimicrobial agents, including some preparations of ritonavir, may contain alcohol that may also precipitate such reactions in persons receiving disulfiram.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Following the development and dissemination of guidelines, the next crucial steps are adoption and implementation. Once practitioners become familiar with the content of guidelines, they can then consider how to change the ways in which they take care of their patients. This may involve changing systems that are part of the office or clinic in which they practice. Changes may be implemented rapidly, especially when clear outcomes have been demonstrated to result from the new practice such as prescribing new medication regimens. In other cases, such as diagnostic screening or oral health delivery, however, barriers emerge which prevent effective implementation. Strategies to promote implementation, such as through quality of care monitoring or dissemination of best practices, are listed and illustrated in the companion document to the original guideline (*HIV clinical practice guidelines*, New York State Department of Health; 2003), which portrays New York's HIV Guidelines Program. The general implementation strategy is outlined below.

- Statement of purpose and goal to encourage adoption and implementation of guidelines into clinical practice by target audience
- Define target audience (providers, consumers, support service providers).
    - Are there groups within this audience that need to be identified and approached with different strategies (e.g., HIV Specialists, family practitioners, minority providers, professional groups, rural-based providers)?
- Define implementation methods.
    - What are the best methods to reach these specific groups (e.g., performance measurement consumer materials, media, conferences)?
- Determine appropriate implementation processes.
    - What steps need to be taken to make these activities happen?
    - What necessary processes are internal to the organization (e.g., coordination with colleagues, monitoring of activities)?

        - What necessary processes are external to the organization (e.g., meetings with external groups, conferences)?
        - Are there opinion leaders that can be identified from the target audience that can champion the topic and influence opinion?
- Monitor progress.
    - What is the flow of activities associated with the implementation process and which can be tracked to monitor the process?
- Evaluate.
    - Did the processes and strategies work?
    - Were the guidelines implemented?
    - What could be improved in future endeavors?

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Aspects of primary care for the HIV-infected substance user. New York (NY): New York State Department of Health; 2004. 17 p. [36 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004

GUIDELINE DEVELOPER(S)

New York State Department of Health - State/Local Government Agency [U.S.]

SOURCE(S) OF FUNDING

New York State Department of Health

GUIDELINE COMMITTEE

Substance Use Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Aspects of primary care for the HIV-infected substance user. Tables and recommendations. New York (NY): New York State Department of Health; 2004 Jun. 11 p. Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108

This guideline is available as a Personal Digital Assistant (PDA) download from the New York State Department of Health AIDS Institute Web site.

PATIENT RESOURCES

None available

NGC STATUS

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